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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/963,239	11/03/97	GOUGH	E 13724-787

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QM12/1117

EXAMINER

PEFFLEY, M

ART UNIT	PAPER NUMBER
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3739

DATE MAILED:

11/17/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/963,239

Applicant(s)

GOUGH ET AL.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☐ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 17) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other:

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Continued Prosecution Application

The request filed on September 29, 1999 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/963,239 is acceptable and a CPA has been established. An action on the CPA follows.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the rigid antenna advancement member must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no description in applicant's specification of a rigid advancement, particularly one that simultaneously advances the antennas from the trocar.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-18, 33-35 and 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16-18 and 33-35 recite the device is used in either a bipolar or a monopolar mode, which is unclear since there is insufficient means (i.e. an energy source) recited in the claims. Applicant must either positively recite the energy source, or amend the language of the rejected claims to indicate that the device is "adapted" to operate in a bipolar or monopolar mode.

Claims 37-39 are unclear with the phrase "electromagnetic energy source to the plurality of antennas". It appears as though "source" should be changed to "is delivered".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 and 15-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over LeVeen et al ('276) in view of the teaching of Edwards et al ('675).

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LeVeen et al discloses a device which comprises a trocar (502) and a multiple antenna ablation device (26) including three or more antennas (24) deployable from the trocar lumen in a lateral direction. Each of the antennas has an ablation surface, and the plurality of antennas are used to create an ablation volume of spheroid shape. The antennas are less rigid than the trocar, and the power range disclosed by LeVeen et al is within the range set forth by the applicant. Further, LeVeen et al teach that the device may be used in either a bipolar or a monopolar mode with the trocar serving as a possible return path.

The only feature not expressly taught by LeVeen et al is the energy delivery surface size which is "sufficient to create a volumetric ablation between the deployed antennas without impeding out a deployed antenna when 5-200 watts of electromagnetic energy is delivered" and the use of an impedance monitoring means. In as much as the LeVeen et al and the applicant's device appear very much similar, the examiner can see no reason why the LeVeen et al device would "impede out". More specifically, there is no specific disclosure in the applicant's specification of the particular size of the energy delivery surface which prevents this "impeding out" of the electrodes. Moreover, it appears one of ordinary skill in the art would obviously be capable of creating the proper energy surface area to prevent impeding out an antenna without undue experimentation.

Edwards et al teach that it is generally well known to monitor the impedance of a multiple electrode RF ablation device so as to avoid unwanted impedance levels (see

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column 13, lines 11-13). Such impedance monitoring and feedback means are generally well known in the art. Edwards et al also disclose the use of sensors (i.e. temperature sensors) located on the electrodes and the sheath (see Abstract), as well as a means to provide a fluid to tissue.

Also, while LeVeen et al disclose the use of a trocar to introduce the multiple antenna ablation device, LeVeen et al fail to disclose the specific size of the trocar. The examiner maintains that use of any well known trocar size would have been an obvious design consideration dependent upon the particular procedure as well as the particular antenna device being used.

With respect to the newly added limitation of a rigid antenna advancement member, the examiner maintains that there is insufficient disclosure of such an advancement member in applicant's specification. Moreover, while LeVeen et al disclose a "cable", the examiner maintains that a cable may be rigid, even if it is capable of being bent. Finally, Edwards et al disclose the use of a rigid advancement mechanism, and providing the LeVeen et al device with a rigid handle and advancement means to simultaneously advance the antennas is deemed an obvious modification to one of ordinary skill in the art.

To have provided the LeVeen et al device with an impedance monitoring and control means to control the delivery of energy to the electrodes to avoid "impeding out" the electrodes would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Edwards et al ('675). Also, it would have been an obvious

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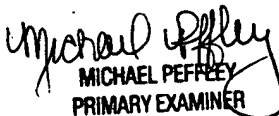
design consideration for one of ordinary skill in the art to have provided the LeVeen et al device with a rigid advancement member to extend the antennas, particularly since Edwards et al use a rigid handle and advancement means to extend the RF antennas.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on 9 hour.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda M Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Michael Peffley/mp
Primary Examiner
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November 15, 1999


MICHAEL PEFFLEY
PRIMARY EXAMINER